

REMARKS/ARGUMENTS

Claims 1, 3, 5-7 and 11-22 are active in this application.

The claims have been amended to clarify the autoantibodies as a rheumatoid arthritis-specific anti-filaggrin autoantibody. Support for this amendment has been previously noted and is found on pages 3, 6-10, 13-14 and 15-17 of the application as originally filed.

Claim 1(b) has been amended to clarify certain features of the citrullinated α -chain of mammalian fibrinogen, which is supported by the specification in Example 2 (starting on page 13).

No new matter is believed to have been added by these amendments.

Claims 1, 3, 5, 7, 11-18 and 22 are drawn to the elected subject matter. With respect to non-elected Claims 6 and 19-21, Applicants request rejoinder of these claims upon finding that the elected protoclaims are allowable.

Applicants confirm that the Notice of Appeal filed on February 11, 2004 was an inadvertent filing as noted in paragraph 5 on page 2 of the Official Action.

The rejection of Claims 1, 5, 7, 10-12 and 22 under 35 U.S.C. § 112, second paragraph is addressed by amendment. Withdrawal of this ground of rejection is requested.

The rejection of Claims 1, 3, 5, 7, 11-18 and 22 under 35 U.S.C. § 112, first paragraph (“new matter”) is respectfully traversed.

As noted above, the autoantibodies have been defined as a “rheumatoid arthritis-specific anti-filaggrin and autoantibodies,” which the Examiner has correctly noted were described in the specification at several locations. The support for these autoantibodies is noted above as well.

Accordingly, withdrawal of this ground of rejection is requested.

The rejection of Claims 1, 3, 5, 7, 10-18 and 22 under 35 U.S.C. § 112, first paragraph (“enablement”) is respectfully traversed.

As set forth in Applicants previous remarks, the specification describes in detail how to purify citrullinated α -fibrin, obtain recombinant fibrinogen, and to test reactivity with rheumatoid arthritis-specific anti-filaggrin autoantibodies (referring to pages 3 and 6-10, pages 10-13, pages 13-14 and pages 15-17). Furthermore, as noted above, the citrullinated α -chain of mammalian fibrinogen has been further characterized where the specification in example 2 of the present application clearly describes how to citrullinate fibrinogen by peptidyl arginine deaminase and demonstrates that the citrullination of fibrinogen facilitates its reaction with anti-filaggrin autoantibodies (see page 16, line 19 to page 1, line 29).

As further evidence that the claimed invention is enabled, Applicants attached hereto a Declaration from one of the named inventors, Dr. Guy Serre. In Dr Serre’s Declaration, he indicates that he had supervised experiments to obtain fibrin fragments recognized by anti-filaggrin autoantibodies (AFA). On the basis of these experiments, his extensive knowledge and experience as set forth in Annex A of the Declaration, Dr. Serre states:

These results are important because they demonstrate that identifying fibrin fragments that react with arthritis-specific anti-filaggrin autoantibodies can be accomplished with routine experimentation involving preparing citrullinated peptides on the basis of known sequences of fibrinogen as described in the above-identified application and testing their reactivity against AFA-positive sera using known immunoassays such as those described in the Examples of the above-identified application. More particularly, the data demonstrate that several peptides recognized by AFAs, representative of the purified citrullinated polypeptide claimed in this application, can be identified from both chains α and β of fibrin by a simple screening with AFA-positive sera.

Accordingly, the specification coupled with the knowledge in the relevant field permits one to make and/or use the full scope of the claimed invention. Withdrawal of this ground of rejection is requested.

The rejection of Claims 1, 3, 5, 7, 10-18 and 22 under 35 U.S.C. § 112, first paragraph (“written description”) is respectfully traversed.

As noted above, the autoantibodies as defined in the claims now recite “rheumatoid arthritis-specific anti-filaggrin autoantibodies”. In addition, the mammalian fibrinogen has been defined according to its modification by peptidyl arginine deiminase which facilitates the reaction with AFA. As noted in Applicants’ previous response, fibrin and fibrinogen α -chain sequences are known. In fact, evidence was provided in support of this knowledge. Citrullinating peptides or fragments of polypeptides is certainly described in the application and the effect thereof on their reactivity with rheumatoid arthritis-specific anti-filaggrin autoantibodies is also described. Accordingly, one of ordinary skill reading the specification when coupled with the knowledge in the art would appreciate that Applicants had possession of the full scope of the claimed invention. Withdrawal of this ground of rejection is requested.

Applicants request allowance of this application without further delay.

Respectfully submitted,

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